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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,934	10/22/2001	Maria Palasis	12013/60402	8212
23838	7590	07/26/2004	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,934

Applicant(s)

PALASIS ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-45 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 38-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-29, 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

The foreign references in the IDS submitted 10/22/01 have not been considered since a copy has not been submitted. The US references have been considered.

Applicant is requested to provide a copy of the references to be considered since the references could not be located with the parent application.

Applicant has not responded to the double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-29,31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Faxom et al. (U.S. Patent No. 5,464,395).

Faxom et al. disclose a catheter system comprising a catheter 5 comprising a shaft having a primary penetrating member 50 and a first penetrating direction and at least one secondary penetrating member 20 wherein each of the at least one secondary penetrating member 20 is retractable and penetrates the tissue in a second different direction that is different from the primary penetrating member. Faxom et al. disclose the second direction to be at an angle that is between 30-90 degrees to the first direction. See col. 5 , lines 57-60. See figures 1,8-19.

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Claims 28-29,31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofling (U.S. Patent No. 5,419,777).

Hofling discloses a catheter system having a catheter comprising a shaft having a primary penetrating member 11 and a first penetrating direction and at least one secondary penetrating member 15 wherein each of the at least one secondary penetrating member 15 is retractable and penetrates the tissue in a second different direction that is different from the primary penetrating member. Hofling discloses the second direction to be lateral to the axial direction as shown in figures 1-3,7. The Examiner is taking the position that the angle is generally perpendicular and between 5-90 degrees.

Claims 28-29 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (U.S. Patent No. 4,578,061).

Lemelson discloses a catheter system having a catheter comprising a shaft having a primary penetrating member and a first penetrating direction and at least one secondary penetrating member 57 or 94 wherein each of the at least one secondary penetrating member 57 or 94 is retractable and penetrates the tissue in a second different direction that is different from the primary penetrating member. Lemelson discloses the second direction to be lateral to the axial direction as shown in figures 3 and 6. The Examiner is taking the position that the angle is generally perpendicular and between 5-90 degrees.

Claims 28-29,30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al. (U.S. Patent No. 5,728,143).

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Gough et al. disclose a first 14 and at least one second 16 penetrating member having different penetrating directions. See figures 1-8.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 28-29,31-32 and 33 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 and 15 of prior U.S. Patent No. 6,319,230. This is a double patenting rejection.

Response to Arguments

Applicant's arguments filed 04/12/04 have been fully considered but they are not persuasive. The Examiner is not in agreement that none of the cited references disclose "at least one secondary member is retractable to a position within a primary penetrating member".

With respect to Faxom et al., the distal portion or end of the outer catheter is considered to be the primary penetrating member and elements 20a,b are considered to be the secondary penetrating members which are retractable within the primary

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member. Applicant appears to be arguing intended use, any device such as a catheter is capable of being a penetrating member. The catheter of Faxom is to be inserted into the body and as such is a penetrating member.

In response to applicant's argument that the catheter or the antenna is not a primary penetrating member, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The same response is applied to the Hofling, Lemelson and Gough references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT